

Appln. No.: 09/373,230
Amdt. dated: October 24, 2008
Reply to Office Action of August 14, 2008

REMARKS

The Office Action has been carefully reviewed. Claims 18, 19 and 24-27 presently appear in this application and define patentable subject matter warranting their allowance.

Reconsideration and allowance are hereby respectfully solicited.

Claims 18, 19, 26 and 27 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is a new matter rejection and is respectfully traversed.

The examiner's position here is analogous to taking the position that by changing the claim language from "comprising" to "consisting of," the claim is no longer supported by the written description. However, this position is untenable. A "comprising" claim includes all of the specifically enumerated species (i.e., one or two), but is open to include other non-enumerated species (i.e., one or more). A "consisting of" claim reads only on the specifically enumerated species, but is not open to the addition of other non-enumerated species. Thus, in the simplest situation, a claim "comprising A+B" certainly discloses A+B but is open to the possibility of other

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ingredients. Changing that claim to "consisting of A+B" does not add new matter as the claim always included at least A+B. While the disclosure of "one or more" does not provide an upper limit, it is clear that "more than one" must necessarily at least be "two" as intended by applicants and as would certainly be recognized and understood by those of ordinary skill in the art. If there is written description support for the minimum plus an unidentified number of others, then there must also be written description support for the minimum. This logic is supported by cases, such as in *In re Wertheim*, 541 F2d 257, 191 USPQ 90 (CCPA 1976), which essentially holds that there is support for the bottom number of a range. A "comprising" claim is akin to an open-ended range. Changing it to "consisting of" limits it to the minimum number in the range. *Wertheim* finds that to be acceptable. See also in *In re Johnson*, 558 F2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). Merely deleting unenumerated possible additional numbers of modifications does not mean that the specification lacks description for the part remaining that was specifically described in the claim.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 18, 19, 24 and 25 have been rejected under 35 USC §112, first paragraph, as containing subject matter which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

In response to the rejection, claim 24 has been amended to further define the protein as one "which can be obtained by recombinant DNA technology based on the amino acid sequence of SEQ ID NO:2".

Applicants believe that claims 18 and 24 define the subject matter for which the specification provides adequate written description. In particular, the specification discloses at page 9, third paragraph to page 14, first paragraph that variants of the polypeptide having the amino acid sequence of SEQ ID NO:2 can be obtained by applying recombinant DNA technology to the amino acid sequence of SEQ ID NO:2, and further discloses at pages 39 to 42, namely in Examples 1 and 2, the concrete methods for obtaining the polypeptide having the amino acid sequence of SEQ ID NO:2 and the variants thereof.

In view of the above, applicants respectfully submit that the present specification substantially discloses the methods for obtaining the polypeptide having the amino acid sequence of SEQ ID NO:2 and the variants thereof in such a way as to reasonably convey to one of skill in the art that the

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applicants, at the time the application was filed, had possession of the claimed invention, when the state of the recombinant DNA technology is taken into account.

Furthermore, at least with regard to "one or two" amino acid modifications recited in claim 26, SEQ ID NO:2 has 157 amino acid residues. Thus, a variant of SEQ ID NO:2 that only has a one or two amino acid residue modification is at least $\frac{155}{157} \times 100\% = 98.7\%$ identical in sequence to SEQ ID NO:2. This situation is analogous to Example 14 (Product by Function) in the USPTO's "Synopsis of Application of Written Description Guidelines", where a claim to a protein having SEQ ID NO:3 and variants thereof that are at least 95% identical (even less than the 98.7% sequence identity required in instant claim 26) and catalyze the reaction of $A \rightarrow B$ was found to satisfy the written description requirement. This Example 14 teaches that:

A review of the claim indicates that variants of SEQ ID NO:3 include but are not limited to those variants of SEQ ID NO:3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO:3.

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO:3 and second being variants of SEQ ID NO:3. There is a single

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species disclosed, that species being SEQ ID NO:3.

There is actual reduction to practice of the single species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO:3 does not have substantial variation since all variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO:3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by members of the genus.

Conclusion: The disclosure meets the requirements of 35 U.S.C. §112 first paragraph as providing adequate written description for the claimed invention.

By analogy, an analysis of the present specification shows that there is actual reduction to practice of a single species, the presently recited polypeptide of SEQ ID NO:2. This single species is representative of the genus because all members have at least 98.7% structural/sequence identity with the reference compound of SEQ ID NO:2 and because of the presence of an assay for the interferon- γ production inducing activity cited

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in the present specification at pages 25-26, Experiment 2-4, and known in the prior art, i.e., Refs. AC (Nakamura et al., 1993) and AD (Okamura et al., 1995) of record. One of ordinary skill in the art would thus conclude that applicants were in possession of the necessary common attributes possessed by members of the genus and thus the disclosure meets the requirements of §112, first paragraph, as providing adequate written description.

Reconsideration and withdrawal of the rejections are respectfully solicited.

Applicants believe that the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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